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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,588	03/09/2006	Taro Yoshikawa	126835	7199

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EXAMINER
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LAU, JONATHAN S

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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08/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/566,588

Applicant(s)

YOSHIKAWA ET AL.

Examiner

Jonathan S. Lau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Specification*

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities:

There is no clearly identified section corresponding to section (g), BRIEF SUMMARY OF THE INVENTION. In the instant application it is unclear if the section titled "Disclosure of the Invention" corresponds to section (g), BRIEF SUMMARY OF

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THE INVENTION; or section (i), DETAILED DESCRIPTION OF THE INVENTION. It is unclear if one of the subsections such as "Means for Solving the Problems" is meant to correspond to section (g), BRIEF SUMMARY OF THE INVENTION.

Section headings should appear in upper case, without underlining or bold type. In the instant application section headings appear underlined in capitalized lower case.

Appropriate correction is required.

The disclosure is objected to because of the following informalities: The following spelling and grammatical errors have been found in the specification:

On page 3, paragraph 1: "in aministration ofa combination", "a demand for makind the burden of patents as little as possible", "injection and the likewhereby the", "administration of small dose".

On page 3, paragraph 2: "conventional product and also has high", "Further, problem in terms of", "contained therein is also resulted."

On page 3, paragraph 3: "high concentrations are improved and a combination drug of glycyrrhizin, aminoacetic acid and cysteine are compounded in which ... the conventional product and are with"

On page 4, paragraph 1: "present invention has been achieved."

On page 5, paragraph 3: "made into pharmaceutical preparations by any of common methods."

On page 6, paragraph 1: "made into a combination drug with other pharmaceutically active ingredient."

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On page 9, paragraph 1: "whereby its utility as pharmaceuticals is very high."

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai et al. (US 6,872,709).

The claims are drawn to a composition containing glycyrrhizin, cysteine, and aminoacetic acid in given concentration ranges. Dependent claims recite the species of

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monoammonium glycyrrhizinate; cysteine hydrochloride; and the composition wherein no sulfite is contained.

Kumagai et al. teaches a composition containing glycyrrhizin ammonium salt, cysteine hydrochloride, and sodium bisulfate but lacking any sulfite salt. See col. 6, lines 5-10. It does not teach this composition in the concentration ranges in the instant application. However, routine experimentation to optimize ranges of concentration would have been obvious to one of ordinary skill in the art at the time the invention was made. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP 2144.05. No such evidence is provided in the instant application.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being an obvious elimination of an element and its function. Claims 2 and 5 recite a composition wherein no sulfite is contained. Omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04. The element of the invention, sulfite, functions to cause the undesirable precipitation of glycyrrhizin and the reduction in the amount of cysteine. See table 1 on page 7 and table 2 on page 8 of specification in the instant application. Further, as recited on page 2 of the specification in the instant application, ingestion of sulfite is associated with overt asthma attacks. See Kollonitsch, column 1 lines 21-23 and 28-29 (US patent US 5,030,645, cited on PTO-892). Removal of this element of the invention, sulfite, removes the function of the element, undesirable precipitation of glycyrrhizin and reduction in the amount of cysteine, and safety problems such as attracting the onset of asthma. Therefore the omission of this

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element of the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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